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| 10/523,268  | 07/07/2005  | John L. Schenk       | XY-lowPressure-USNP                | 5591                        |
| 88484   | 7590        | 11/10/2010           |                                    |                             |
| CR MILES P.C.<br>405 Mason Court, Suite 119<br>Fort Collins, CO 80524 |             |                      | EXAMINER<br>NOBLE, MARCIA STEPHENS |                             |
|   |             |                      | ART UNIT<br>1632                   | PAPER NUMBER                |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/523,268 | <b>Applicant(s)</b><br>SCHENK ET AL. |  |
|                              | <b>Examiner</b><br>MARCIA S. NOBLE   | <b>Art Unit</b><br>1632              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,8,31,39-52 and 62-72 is/are pending in the application.
- 4a) Of the above claim(s) 41-52 and 62-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,8,31,39,40 and 65-72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Withdrawn Rejections/Objections***

The rejection of claims 65-72, under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn.

Applicant amended claim 65 to recite "sperm cell viability" and "oocyte cleavage rate" as recommended to obviate this rejection.

The objection to claim 1 and its dependent claims for reciting, "obtaining a sperm cell from a male of a species of mammal", is withdrawn.

Applicant amended this recitation as recommended and thus overcome the objection.

The objection to claim 1 and its dependents for reciting, "generating....a sheath fluid selected from a group consisting of...", is withdrawn. Applicant removed this limitation, rendering the objection moot.

The objection to claim 2 for reciting, "a species of mammal" numerous times, is withdrawn. Applicant amended claim 2 to remove this recitation thus overcoming the objection.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 8, 33, and 65-69, as amended or previously presented, are rejected under 35 U.S.C. 102(b) as being anticipated by Rath et al (J Anim Sci 77:3346-3352, 1999; of record in IDS).

Rath et al discloses a method of sorting sperm by sex and determining its ability to generate embryos by in vitro fertilization. Their method is comprised of collecting sperm from boars (p. 3347, col 2, par 1, line 1-2), subjecting the sperm to flow cytometry, and determining the generation of embryos produced by in vitro fertilization (a measure of fertility characteristics) with sex sorted sperm or unsorted sperm (p. 3348 in total). The flow cytometry consisted of generating a flow and entraining sperm samples into the fluid stream (p. 3348, col 1). They disclose that the fluid sheath was PBS (p. 3348, col 1). They disclosed that they adjusted the fluid stream flow through the adjustment of pressure to using high-speed sperm sorting with a fluid sheath pressure of  $2.81 \text{ kg/cm}^2$ , which is approximately 40 psi, to improve sorting and fertility characteristics over standard speed sorting (p. 3346, col 2, lines 3-7 and p. 3348, col 1). They disclosed that sperm motility following sorting was 60% in all cases (p. 3349, col 1). They also disclose fertilization rates and oocyte cleavage rates, which also indicates that the sperm is viable and can serve as a measure of sperm viability as claimed.

### ***Response to Arguments***

Applicant's arguments filed 8/23/2010 have been fully considered but they are not persuasive. Applicant asserts that the amended claims now recite between about 30 psi and about 40 psi which overcomes Rath et al.

As discussed above and reiterated here Rath et al discloses that they adjusted the fluid stream flow through the adjustment of pressure to using high-speed sperm sorting with a fluid sheath pressure of  $2.81 \text{ kg/cm}^2$ , which is approximately 40 psi, to improve sorting and fertility characteristics over standard speed sorting (p. 3346, col 2, lines 3-7 and p. 3348, col 1). Thus, contrary to Applicant's assertion, Rath discloses the claimed range of about 30 to about 40 psi because that discloses about 40 psi. Thus, Rath discloses the limitation of the amended claims and Applicant's arguments are not found persuasive.

Claims 1-3, 8, 31, 39, 40, and 65-72 are objected to because of the following informalities:

Claim 65, and its dependent claims still recite, "obtaining a sperm cell from a male of a species of mammal". The recitation of "a sperm cell from a male" is redundant because a sperm cell can only be obtained from a male. Amending the first step to recite, "obtaining a sperm from a mammal" would be remedial. It is recommended, but not required to remove the recitations of "of a species". This recitation does not add any breadth to the claims and makes the recited "obtaining" step cumbersome.

Claim 1 and its dependents recite, "generating....a sheath fluid selected from a group consisting of..." This recitation should be amended to recite,

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"generating...a sheath fluid selected from the group consisting of..." because "a group" suggests there are more than one possible group and there are no other possible groups from which to select.

Claim 1, 65, and their dependents recite, "selecting at least one desired sperm cell fertility characteristic, said at least one fertility characteristic selected from a group consisting of...". The recitations of "selected from a group consisting of" suggests that there are other possible groups to select from. However, no other groups exist in the specification. Amending the claims to recite, selecting at least one desired sperm cell fertility characteristic selected from the group consisting of...." would be remedial. It is also recommended to remove the recitations of, "said at least one fertility characteristic". This recitation is redundant, make the claim cumbersome, and difficult to follow.

Claims 66 still recites "a species of mammal" numerous time. These recitations are redundant, do not further clarify such recitations as "bovine, equine, porcine", etc..., and make the claim cumbersome. Removing all the recitations of "a species of mammal" would be remedial.

Claims 3 and 67 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Independent claims 1 and 65 recite "generating a fluid stream...comprising a sheath fluid." Dependent claims 3 and 67 further specify, "said fluid stream comprises a sheath fluid stream". However, as described

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above the independent claim already states that the fluid stream is a fluid sheath stream. Therefore, claims 3 and 67 are not further limiting.

Claims 8 and 69 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 8 and 69 specifies that the fluid stream is generated by a flow cytometry or cell sorter. However, at the time of the invention, there was no other means of generating a fluid stream for subjecting sperm than use of a flow cytometry or cell sorter. Thus, the claim inherently is not further limiting. If Applicant can provide evidence that other means could have been used, the objection can be withdrawn. Otherwise, the claim should be cancelled.

Appropriate correction is required.

### ***Examiner's Comment about Objections***

Applicant did not address the objections in their remarks. Applicant did address and overcome some of the objections by amending the claims. However, Applicant did not address all the objections. Thus, the above objections that were not addressed by the amendments are maintained.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall— conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 8, 31, 39, 40 and 65-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, 65, and its dependents recite, "oocyte blastocyst rate". This recitation is indefinite because oocytes do not have a "blastocyst rate". Embryos, fertilized oocytes, and zygotes form blastocyst, but oocytes do not. Amending the claims to solely recite "blastocyst rate" would overcome this limitation. An artisan would not understand what is meant by "blastocyst rate".

Claim 1, 65, and its dependents recite, "altering said flow characteristics of said fluid stream to adjust fluid stream pressure....". This recitation is indefinite because "altering" or "adjusting" the fluid stream pressure suggests that prior to this step some other fluid stream pressure has been designated. However, no such fluid stream pressure has been designated. It seems that Applicant may be choosing this language to try and suggest that different fluid streams are chosen for the fluid stream pressure depending upon the fertility characteristic desired. However, these recitations are not making this apparent. Below in the Examiner's comment, an example of a possible amendment for claim 1 has been provided that may clarify applicants intend for the claimed invention.

Claim 1, 65, and its dependent recites, "subjecting said sperm cell ...to said fluid stream". These claims then recite, "entraining said sperm cell into said fluid stream. These combined recitations are indefinite because it is not apparent how entraining the sperm samples differ from subjecting the sperm samples.



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These claims further recite, "controlling said ...sperm cell fertility selected through adjustment of said fluid stream. It is not apparent how the active "controlling" step differs from the combined altering and subjecting steps that precede the controlling steps. Amending the claims to remove the entraining and controlling steps would be remedial. See the example in the Examiner's comment for potential alternative language that will clarify these issues.

Claims 1, 65, and their dependents are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: collecting the sperm cells subjected to the fluid stream, thereby generating an insemination sample with a desired sperm cell fertility characteristic. The claims recite generation a sperm cell insemination sample that subjects the sperm to a fluid stream and does not necessarily collect the sperm subjected to the fluid stream. To obtain such an insemination sample the subjected sperm needed to be collected. Therefore, a collection step is required.

Claim 31 recites the limitation "said pregnancy rate of a female of said bovine species of mammal". There is insufficient antecedent basis for this limitation in the claim. The independent claim only recites a species of mammal. The independent claim never species bovine or pregnancy rate of a bovine. Thus, dependent claim 31 lack antecedent basis. Claims 39 and 40 depend from claim 31 and thus are also indefinite.

Claim 31 recites, "wherein said pregnancy rate of a female of said bovine species of mammal inseminated with a bovine sperm cell insemination sample

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having controlled sperm cell fertility characteristics". This clause is incomplete. It defines a subject of the clause, "said pregnancy rate" but does not specify what happens to said pregnancy rate. The clause is at least missing a verb and possibly a direct object. Thus, the clause of claim 31 is incomprehensible and thus indefinite. Claim 70 has similar claim language as claim 31 except claim 70 recites, said pregnancy rate comprises a pregnancy rate...". If Applicant's intent is to further describe the pregnancy rate as is done in claim 70, amending the claim to have a similar recitation as that in claim 70 would be remedial. For art purposes, wherein clause of claim 31 is being interpreted as wherein the pregnancy rate comprises a pregnancy rate of a cow inseminated with a bovine sperm cell insemination sample having controlled sperm cell fertility characteristics, as is recite in claim 70.

Claim 1, 65, 31, 39, 40, and 70-72 recite, "sample having controlled sperm cell fertility characteristics". This recitation is indefinite because it is not apparent how the fertility characteristic is "controlled" in the sperm.

***Examiner's Comment about the 112, 2<sup>nd</sup> Paragraph Rejections***

Applicant did not address all of the rejections in their remarks. Applicant did address and overcome some of the rejections by amending the claims. However, Applicant did not address all the rejections. Thus, the above rejections that were not addressed by the amendments are maintained.

***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31, 39, and 70-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rath et al (J Anim Sci 77:3346-3352, 1999; of record in IDS) in further view of Ax (US 4683213 patent date: 7/28/1997).

Rath teaches the claimed invention as discussed above. Rath does not explicitly teach that pregnancy rates obtained by inseminating cows with sperm from the insemination sample, as recited in claims 31 and 70. Further, Rath does not explicitly teach the insemination sample has the specified sperm cell concentrations, as specified in claims 39, 71, and 72. However, the limitations of these claims are not active method steps in the claims, thus implicitly the method taught by Rath should result in the pregnancy rates and sperm cell concentrations as claimed.

Rath does not teach that the method is used in a bovine. However, at the time the inventions was made methods for more easily predicting sperm fertility characteristics and sex characteristic in cattle were desired (see Ax col 1, line 14 to col 2, line 3). Therefore, it would have been obvious to an ordinary artisan at the time of filing to apply the method of Rath to bovine sperm with a reasonable expectation of success. Further an artisan would have been motivated to apply the method of Rath to bovine sperm because as taught by Ax traditional methods

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of determining fertility of bovine sperm are lengthy and time consuming and that methods that would more easily predict sperm fertility and sex in cattle would be beneficial.

The combination of prior art cited above in all rejections under 35 U.S.C. 103 satisfies the factual inquiries as set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Once this has been accomplished the holdings in KSR can be applied (*KSR International Co. v. Teleflex Inc. (KSR)*, 550 U.S. 389, 82 USPQ2d 1385 (2007): "Exemplary rationales that may support a conclusion of obviousness include: (A) Combining prior art elements according to known methods to yield predictable results; (B) Simple substitution of one known element for another to obtain predictable results; (C) Use of known technique to improve similar devices (methods, or products) in the same way; (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (E) "Obvious to try" - choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention." In the present situation, rationales A, B, and G are applicable. The claimed method was known in the art at the time of filing as indicated by Rath and Ax. Thus, the teachings of the cited prior art in

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the obviousness rejection above provide the requisite teachings and motivations with a clear, reasonable expectation. The cited prior art meets the criteria set forth in both Graham and KSR.

***Examiner's Comment about the 103a Rejection***

Applicant did not address the 103a rejection in the remarks and the amendment to the claims did not overcome the art. Thus the rejection of record in maintained.

***Examiner's Comment***

In the remarks, Applicant asserts that the amendments to the claims overcome the 112, 1st paragraph rejection. Applicant's arguments are in error because a 112, 1<sup>st</sup> paragraph rejection is not pending.

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MARCIA S. NOBLE** whose telephone number is (571)272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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